PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Kenneth T. Heruth and Keith A. Miesel	Confirmation No.	8232
Serial No.:	10/825,964		
Filed:	April 15, 2004	Customer No.:	28863
Examiner:	Fangemonique A. Smith		
Group Art Unit:	3736		
Docket No.:	1023-360US01		
Title:	DETECTING SLEEP		

APPEAL BRIEF

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Alexandria, VA 22313-1450

Sir:

This is an Appeal Brief in support of an appeal from the final Office Action mailed on March 23, 2009, which finally rejected claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73, and the Advisory Action mailed on July 9, 2009, which maintained the rejection of the claims. The Notice of Appeal was filed on July 30, 2009. The period for filing this Brief runs through September 30, 2009.

Please charge Deposit Account No. 50-1778 in the amount of $540.00 to cover the required fee for filing this Appeal Brief for a large entity. Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

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REAL PARTY IN INTEREST

The Real Party of Interest is Medtronic, Inc. of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

A Notice of Appeal for U.S. Patent Application Serial No. 11/081,786, which is a continuation-in-part of the present application, was filed on July 30, 2009. No decisions have been rendered by the Board for U.S. Patent Application Serial No. 11/081,786.

STATUS OF CLAIMS

Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 are pending and are the subject of this Appeal. The claims on appeal are set forth in Appendix A.

Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72, and 73 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application No. 2005/0042589 to Hatlestad et al. (hereinafter "Hatlestad") in view of U.S. Patent No. 7,207,947, to Koh et al. (hereinafter "Koh").

Claim 1-19, 24, 25, 34, 39, 41, 42, 46-52, 54, 56 and 63-71 were previously canceled.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final Office Action mailed March 23, 2009, from which this Appeal has been made.

SUMMARY OF CLAIMED SUBJECT MATTER

The pending claims relate generally to systems for determining respective values for each of a plurality of sleep metrics that each indicate a probability of a patient being asleep.[1] The systems determine each of the sleep metric values based on the current value of a respective one of a plurality of physiological parameters of the patient.[2] Use of sleep metrics that indicate a probability of the patient being asleep for each of a plurality of physiological parameters may increase the reliability with which an implantable medical device may determine whether a patient is asleep.[3]

Independent claim 53 recites a medical system comprising a plurality of sensors, each of the sensors generating a signal as a function of at least one physiological parameter of a patient[4] and an implantable medical device that includes a processor to monitor a plurality of physiological parameters based on the signals output by the sensors[5], wherein the plurality of physiological parameters comprise at least one of blood pressure, muscular activity, arterial blood flow, or galvanic skin response[6], for each of the plurality of physiological parameters, determine a respective one of a plurality of sleep metric values, each of the sleep metric values indicating a non-binary probability of the patient being asleep based on the respective physiological parameter[7], and mathematically combine the plurality of sleep metric values that each indicate that probability of the patient being asleep based on the respective one of the plurality physiological parameters to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep.[8] Claims 55 and 57-62 are dependent on claim 53.

Independent claim 72 recites a medical system comprising a plurality of sensors, each of the sensors generating a signal as a function of at least one physiological parameter of a patient[9] and an implantable medical device that includes a processor that monitors a plurality of

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[1] Paragraphs [0020] and [0039].
[2] Paragraph [0007].
[3] Paragraph [0020].
[4] Paragraphs [0008] and [0047]-[0054].
[5] Paragraphs [0009], [0034], [0035], [0039], [0048], [0055] and [0060].
[6] Paragraphs [0008], [0035] and [0048].
[7] Paragraphs [0007], [0011], [0020], [0036], [0038], [0039], [0057] and [0061].
[8] Paragraphs [0011], [0020], [0038], [0039], [0057], [0058] and [0061].
[9] Paragraphs [0008] and [0047]-[0054].

physiological parameters of the patient based on the signals output by the sensors[10], for each of the plurality of physiological parameters, determines a respective one of a plurality of sleep metric values, each of the sleep metric values indicating a non-binary probability of the patient being asleep based on the respective physiological parameter[11], and mathematically combines the plurality of sleep metric values that each indicate the non-binary probability of the patient being asleep based on the respective one of the plurality physiological parameters to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep.[12] Claims 20-23, 26-33, and 35-38 are dependent on claim 72.

Independent claim 73 recites a system comprising means for monitoring a plurality of physiological parameters of a patient[13], implantable means for determining a respective one of a plurality of sleep metric values for each of the plurality of physiological parameters, each of the sleep metric values indicating a non-binary probability of the patient being asleep based on the respective physiological parameter[14], and implantable means for mathematically combining the plurality of sleep metric values that each indicate the non-binary probability of the patient being asleep based on the respective one of the plurality physiological parameters to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep.[15] Claims 40 and 43-45 are dependent on claim 73.

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[10] Paragraphs [0009], [0034], [0035], [0039], [0048], [0055] and [0060].
[11] Paragraphs [0007], [0011], [0020], [0036], [0038], [0039], [0057] and [0061].
[12] Paragraphs [0011], [0020], [0038], [0039], [0057], [0058] and [0061].
[13] Paragraphs [0009], [0034], [0035], [0039], [0048], [0055] and [0060].
[14] Paragraphs [0007], [0011], [0020], [0036], [0038], [0039], [0057],and [0061].
[15] Paragraphs [0011], [0020], [0038], [0039], [0057], [0058] and [0061].

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The ground of rejection to be reviewed on appeal is the final rejection of claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 under 35 U.S.C. § 103(a) as being unpatentable over Hatlestad in view of Koh.

ARGUMENT

1. Rejection of Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 as Being Obvious over Hatlestad in View of Koh

The Examiner's final rejection of claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 was in error. Appellant respectfully requests reversal of the rejection by the Board of Patent Appeals based on the arguments below.

In the final Office Action, the Examiner cited Hatlestad as teaching the requirements of independent claims 53, 72, and 73, including monitoring a plurality of physiological parameters based on signals output from sensors, determining a plurality of sleep metric values based on respective physiological parameters, and determining a value of an overall sleep metric by averaging the values of a plurality of sleep metrics.[16] The Examiner acknowledged that Hatlestad does not disclose that the sleep metric values indicate a non-binary probability of the sleep state of the patient, as required by each of the independent claims.[17] To overcome this admitted deficiency of Hatlestad, the Examiner suggested modifying the sleep evaluation device of Hatlestad to determine the probability of sleep in a subject, which the Examiner argued is taught by Koh.

However, contrary to the Examiner's argument, Koh also fails to teach or suggest determining a non-binary probability of sleep in a subject. Accordingly, even if Hatlestad were modified in view of Koh, the resulting combination would not disclose or suggest each and every element of independent claims 53, 72 and 73.

Neither Hatlestad nor Koh discloses or suggests determining a plurality of sleep quality metrics that each indicate a non-binary probability of the patient being asleep based on a

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[16] Final Office Action dated March 23, 2009, pages 2-4, item 3.
[17] *Id.* at page 4, item 3.

respective physiological parameter, as required by Appellant's independent claims. Additionally, neither Hatlestad nor Koh discloses or suggests mathematically combining a plurality of sleep metric values that each indicate a non-binary probability of the patient being asleep to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep, as required by Appellant's independent claims. Contrary to the Examiner's assertions, neither Hatlestad nor Koh discloses or suggests any sleep metric that indicates the non-binary probability of a patient being asleep.

Hatlestad describes a sleep detection unit including two sensors.[18] The first sensor is a sleep detection sensor that detects a first sleep-related condition.[19] The first sleep-related condition is compared to a sleep threshold to detect sleep onset and termination.[20] The second sensor is a threshold adjustment sensor that detects a second sleep-related condition.[21] The second sleep-related condition is used to adjust the sleep threshold to which the first sleep-related condition is compared.[22] The sleep threshold may be increased or decreased depending on the value of the second sleep-related condition.[23] The sleep detection unit compares a value of the first sleep-related condition to the sleep threshold and makes a binary determination of whether the patient is asleep based on the comparison.[24] As acknowledged by the Examiner, neither of the first and second sleep related conditions indicates a non-binary probability of a patient being asleep, as required by the independent claims.

Koh describes making a binary determination of whether a patient is asleep or awake based on a variety of parameters that generally vary with circadian state.[25] In particular, Koh describes combining various circadian parameters together to yield a single value or metric representative of the current circadian state.[26] The metric is compared against threshold values indicative of whether the patient is asleep or awake.[27] Although each of the circadian parameters

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[18] Hatlestad, paragraphs [0081] and [0082].
[19] *Id.* at paragraph [0082].
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.* at paragraph [0087].
[24] *Id.* at paragraph [0084].
[25] Koh, column 11, lines 12-29.
[26] *Id.* at column 11, lines 16-18.
[27] *Id.* at column 11, lines 26-28.

may be normalized and averaged together[28], none of the individual parameters indicates a ***non-binary probability*** of the patient being asleep and the combined metric does not indicate an overall ***non-binary probability*** of the patient being asleep. The Koh values are raw or normalized physiological parameter values, rather than probabilities.

Neither Hatlestad nor Koh discloses or suggests determining a plurality of sleep quality metrics that each indicate a non-binary probability of the patient being asleep based on a respective physiological parameter, as required by Appellant's independent claims. Additionally, neither Hatlestad nor Koh discloses or suggests mathematically combining a plurality of sleep metric values that each indicate a non-binary probability of the patient being asleep to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep, as required by Appellant's independent claims. Contrary to the Examiner's assertions, neither Hatlestad nor Koh discloses or suggests any sleep metric that indicates the probability of a patient being asleep.

Additionally, the Examiner's characterization of Hatlestad is incorrect. For example, the Examiner cited paragraphs [0090]-[0103] of Hatlestad as describing a process of determining an overall sleep metric value by averaging values of a plurality of sleep metrics.[29] However, the cited portion of Hatlestad discusses a binary sleep detection method that utilizes an activity sensor as the sleep detection sensor and a minute ventilation sensor as the threshold adjustment sensor. The method determines the sleep threshold value based on the minute ventilation sensor, and compares the patient's activity level to the threshold value to detect sleep onset and termination. The patient's heart rate is also monitored to confirm that the patient is asleep when sleep onset is detected. A specific combination of values of activity level, minute ventilation, and heart rate indicate that the patient is in fact asleep (i.e., an activity level below a threshold value determined by the minute ventilation value in combination with a sleep-compatible heart rate).

The activity level, minute ventilation, and heart rate are not mathematically combined in the example method of Hatlestad cited by the Examiner. Although the values are used together, in the manner described above, they are not in any way mathematically combined. Instead, the

[28] *Id.* at column 11, lines 18-20.
[29] Final Office Action dated 3/23/09, page 3.

minute ventilation is used to adjust the sleep threshold. The patient's activity is compared to the threshold value to make a binary determination of whether the patient is asleep. Use of minute ventilation to determine the activity threshold is not a mathematical combination of the minute ventilation and activity values.

If it is determined that the patient is asleep based on the comparison, a second binary determination of whether the heart rate is compatible with sleep is determined. An additional comparison of heart rate to a threshold in a process in which activity and minute ventilation values are also considered is not a mathematical combination of the heart rate value with the activity and minute ventilation values. If both binary determinations indicate sleep, sleep onset is confirmed. If the heart rate is incompatible with sleep, minute ventilation and patient activity continue to be monitored.

The two determinations of sleep state are not mathematically combined to determine an overall probability of the patient being asleep. Instead, they are compared to provide a binary determination of whether the patient is asleep. Hatlestad does not discuss determining an overall probability of the patient being asleep and, instead, describes making a binary determination that the patient is asleep.

Furthermore, the Examiner incorrectly characterizes sleep quality metrics described by Hatlestad as a plurality of sleep metrics that each indicate whether the patient is asleep. In particular, in the final Office Action, the Examiner cited paragraphs [0135]-[0162] of Hatlestad as teaching determining a value of each of a plurality of sleep metrics, each of the plurality of sleep metric values determined based on a respective one of the physiological parameters.[30] However, the cited portion of Hatlestad describes a variety of sleep quality metrics, which are completely unrelated to the sleep detection process described in Hatlestad's paragraphs [0090]-[0103]. Appellant's claims require that the plurality of sleep metric values that each indicate the probability of the patient being asleep based on the respective one of the plurality physiological parameters are mathematically combined to determine an overall sleep metric value that indicates an overall probability of the patient being asleep. The Hatlestad sleep detection process, described in Hatlestad's paragraphs [0090]-[0103], is completely unrelated to

[30] *Id.* at page 3.

the sleep quality metrics described by Hatlestad, described in Hatlestad's paragraphs [0135]-[0162]. The Hatlestad sleep detection method does not use any of the sleep quality metric values to detect sleep onset and termination, much less mathematically combine a plurality of sleep quality metric values. For at least these reasons, the Examiner's characterization of Hatlestad is incorrect.

Appellant's claims further require that the plurality of sleep quality metric values each indicate a probability of the patient being asleep. The Examiner acknowledged that Hatlestad does not disclose or suggest how the sleep metric values indicate a probability of the patient being asleep. It is clear that the sleep quality metrics described in Hatlestad do not indicate a probability of the patient being asleep. As one example, Hatlestad teaches that undisturbed respiration sleep time may be calculated by subtracting sleep time in disturbed breathing from the total time asleep. The total time asleep may be determined using the binary sleep detection of Hatlestad discussed above. Hatlestad also describes disordered breathing detection methods that are used to determine sleep time in disturbed breathing.

Neither the undisturbed respiration sleep time, nor the sleep time in disturbed breathing, indicate a probability of the patient being asleep. None of the sleep quality metrics described in paragraphs [0135]-[0162] indicates a probability of the patient being asleep. As previously discussed, Hatlestad describes a sleep detection unit that determines whether the patient is asleep. The sleep quality metrics described in paragraphs [0135]-[0162] quantify the quality of the patient's sleep, and do not indicate a probability of the patient being asleep.

Neither Hatlestad nor Koh disclose or suggest determining a plurality of sleep quality metrics that each indicate a probability of the patient being asleep based on a respective physiological parameter. Additionally, neither Hatlestad nor Koh disclose or suggest mathematically combining a plurality of sleep metric values that each indicate a probability of the patient being asleep to determine an overall sleep metric value that indicates an overall probability of the patient being asleep. In fact, neither Hatlestad nor Koh disclose or suggest any sleep metric that indicates the probability of a patient being asleep.

Claims 20-23, 26-33, 35-38, 40, 43-45, 55, and 57-62 depend from one of independent claims 53, 72, and 73, and are patentable over Hatlestad in view of Koh for at least the reasons discussed above with respect to the independent claims.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Appellant's claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72, and 73 under 35 U.S.C. § 103(a). The rejection of claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72, and 73 is in error and must be reversed.

CONCLUSION

The Examiner has failed to meet the burden of establishing a *prima facie* case of obviousness with respect to claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72, and 73. In view of Appellant's arguments, the final rejection of Appellant's claims is improper and should be reversed. Reversal of all pending rejections and allowance of all pending claims is respectfully requested. Appellant respectfully requests separate review by the Board for each set of claims argued under a separate heading.

Date: 9-30-09

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APPENDIX A

THE CLAIMS ON APPEAL

20. The system of claim 72, wherein the physiological parameters comprise at least one of activity level, posture, heart rate, respiration rate, respiratory volume, or core temperature.

21. The system of claim 72, wherein physiological parameters comprise at least one of blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity, arterial blood flow, or galvanic skin response.

22. The system of claim 72, wherein the processor determines a variability of at least one of the physiological parameters, and determines the sleep metric value for the physiological parameter based on the variability.

23. The system of claim 72, wherein the processor determines at least one of a mean value and a median value of at least one of the physiological parameters, and determines the sleep metric value for the physiological parameter based on the at least one of the mean value and the median value.

26. The system of claim 72, wherein the processor determines the value of the overall sleep metric by averaging the values of the plurality of sleep metrics.

27. The system of claim 26, wherein the processor applies a weighting factor to at least one of values of the plurality of sleep metrics.

28. The system of claim 72, further comprising a memory to store a threshold value, wherein the processor compares the value of the overall sleep metric to the threshold value and determines whether the patient is asleep based on the comparison.

29. The system of claim 28, wherein the memory stores a plurality of threshold values, and the processor compares the value of the overall sleep metric to each of the threshold values and determines a sleep state of the patient based on the comparison.

30. The system of claim 29, wherein the processor determines whether the patient is in one of a rapid eye movement (REM) sleep state or a nonrapid eye movement (NREM) sleep state.

31. The system of claim 28, further comprising a user interface, wherein a user selects the threshold via the user interface.

32. The system of claim 28, wherein the processor controls delivery of a therapy to the patient by the implantable medical device based on the determination of whether the patient is asleep.

33. The system of claim 28, wherein the processor stores information indicating when the patient is asleep within the memory for retrieval by a user.

35. The system of claim 72, wherein the implantable medical device includes at least one of the sensors.

36. The system of claim 72, wherein the implantable medical device is coupled to at least one of the sensors via a lead.

37. The system of claim 72, wherein the implantable medical device is wirelessly coupled to at least one of the sensors.

38. The system of claim 72, wherein the implantable medical device comprises at least one of an implantable neurostimulator or an implantable pump.

40. The system of claim 73, further comprising means for generating at least one signal as a function of the physiological parameters, wherein the means for monitoring comprises means for monitoring the physiological parameters based on the signal.

43. The system of claim 73, further comprising means for comparing the value of the overall sleep metric to a threshold value and determining whether the patient is asleep based on the comparison.

44. The system of claim 43, further comprising:

means for delivering a therapy to the patient; and

means for controlling delivery of a therapy to the patient by the therapy delivery means based on the determination of whether the patient is asleep.

45. The system of claim 43, further comprising means for storing information indicating when the patient is asleep for retrieval by a user.

53. A medical system comprising:

a plurality of sensors, each of the sensors generating a signal as a function of at least one physiological parameter of a patient; and

an implantable medical device that includes a processor to:

monitor a plurality of physiological parameters based on the signals output by the sensors, wherein the plurality of physiological parameters comprise at least one of blood pressure, muscular activity, arterial blood flow, or galvanic skin response,

for each of the plurality of physiological parameters, determine a respective one of a plurality of sleep metric values, each of the sleep metric values indicating a non-binary probability of the patient being asleep based on the respective physiological parameter, and

mathematically combine the plurality of sleep metric values that each indicate that probability of the patient being asleep based on the respective one of the plurality physiological parameters to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep.

55. The system of claim 53,

wherein the implantable medical device further comprises a memory to store a threshold value, and

wherein the processor compares the value of the overall sleep metric to a threshold value, and determines whether the patient is asleep based on the comparison.

57. The system of claim 53, wherein the processor controls delivery of a therapy to the patient based on the determination of the overall non-binary probability of the patient being asleep.

58. The system of claim 53,

wherein the implantable medical device further comprises a memory, and

wherein the processor stores information indicating when the patient is asleep within the memory for retrieval by a user.

59. The system of claim 53, wherein the implantable medical device includes at least one of the sensors.

60. The system of claim 53, wherein the implantable medical device is coupled to at least one of the sensors via a lead.

61. The system of claim 53, wherein the implantable medical device is wirelessly coupled to at least one of the sensors.

62. The system of claim 53, wherein the implantable medical device comprises at least one of an implantable neurostimulator or an implantable pump.

72. A medical system comprising:

a plurality of sensors, each of the sensors generating a signal as a function of at least one physiological parameter of a patient; and

an implantable medical device that includes a processor that:

monitors a plurality of physiological parameters of the patient based on the signals output by the sensors,

for each of the plurality of physiological parameters, determines a respective one of a plurality of sleep metric values, each of the sleep metric values indicating a non-binary probability of the patient being asleep based on the respective physiological parameter, and

mathematically combines the plurality of sleep metric values that each indicate the non-binary probability of the patient being asleep based on the respective one of the plurality physiological parameters to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep.

73. A system comprising:

means for monitoring a plurality of physiological parameters of a patient;

implantable means for determining a respective one of a plurality of sleep metric values for each of the plurality of physiological parameters, each of the sleep metric values indicating a non-binary probability of the patient being asleep based on the respective physiological parameter; and

implantable means for mathematically combining the plurality of sleep metric values that each indicate the non-binary probability of the patient being asleep based on the respective one of the plurality physiological parameters to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep.

APPENDIX B

EVIDENCE

NONE

APPENDIX C

RELATED PROCEEDINGS

NONE